

Dockets Management Branch
Food and Drug Administration
April 12, 2006

Attachment 4

Hydrocodone Bitartrate/Acetaminophen Petition (Docket 02P-0233)

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May 20, 2002

VIA MESSENGER

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
HFA-305, Room 1061
5630 Fishers Lane
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned submits this petition in quadruplicate, pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act and 21 CFR § 314.93, on behalf of a client, to request that the Commissioner of Food and Drugs permit the filing of an Abbreviated New Drug Application (ANDA) for a drug that has the same strengths as a drug listed in FDA's publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," but differs in dosage form.

A. Action Requested

By this petition, the Commissioner of the Food and Drug Administration (FDA) is hereby requested to declare that Hydrocodone Bitartrate and Acetaminophen Orally Disintegrating Tablets, 5 mg / 500 mg are suitable for submission as an ANDA. The Reference Listed Drug (RLD) product upon which this petition is based is Vicodin® (hydrocodone bitartrate and acetaminophen tablets, USP), 5 mg / 500 mg. Therefore, the petitioner requests a change from the RLD, Abbott's Vicodin, only in its dosage form (from tablet to orally disintegrating tablet).

B. Statement of Grounds

The Federal Food, Drug and Cosmetic Act provides for the submission of an ANDA for a drug product that differs in dosage form from that of the listed drug provided the FDA

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has approved a petition that proposed filing such an application. A copy of the most recent internet listing of the "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book), included in Attachment 1, lists the RLD, Abbott's Vicodin. The proposed drug product is an orally disintegrating form of the tablet, in the same dosage strengths as the RLD. The proposed product contains the same active ingredients in the same strengths as the RLD and is intended for the same route of administration. Thus, the proposed product will be labeled with the same conditions of use as the listed drug and is expected to have the same therapeutic effect when used as indicated in the labeling.

A copy of the RLD labeling is included in Attachment 2. The labeling of the proposed product is expected to be the same as that for the RLD with the exception of the section denoting the manufacturer, and the change in dosage form, which will instruct the user to place the orally disintegrating tablet on the tongue, allowing it to rapidly disintegrate and be swallowed. A copy of the draft proposed package insert is provided in Attachment 3.

In support of the change in dosage form requested in this petition, the petitioner would like to point out that the Agency has previously approved ANDA suitability petitions allowing for a change in dosage form in many instances. A suitability petition was recently approved for the drug product famotidine (docket OOP-1422) to allow a change from a tablet to an orally disintegrating tablet. The petitioner is seeking the change in dosage form in an effort to make an alternate dosage form (orally disintegrating tablet) available to those individuals that may have difficulty in swallowing an intact tablet or prefer the proposed dosage form.

The petitioner is also requesting a waiver of the requirement to conduct pediatric studies in accordance with the Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drug and Biological Products in Pediatric Patients; Final Rule (Pediatric Final Rule) 63 FR 66632 published December 2, 1998, and the waiver requirements set forth in 21 CFR § 314.55(c)(2)(i), as "the drug product does not represent a meaningful therapeutic benefit over existing treatments for pediatric patients and is not likely to be used in a substantial number of pediatric patients". The petitioner notes that alternative pain remedies are presently approved for use in pediatric patients. Currently approved analgesics include acetaminophen elixir, Lortab Elixir, Tylenol with Codeine Elixir, Ibuprofen Drops/Suspension and Demerol Syrup. Therefore, a number of approved analgesic products exist in dosage forms for use in the pediatric population and are labeled for pediatric use. While dosing for pediatric patients under 2 years is not currently included in the labeling for these products, the monograph for Opioid (Narcotic) Analgesics and Acetaminophen included in Drug Information for the Health Care Professional (USP DI 2002, 22nd Edition) states that children up to 2 years of age are more susceptible to the effects of opioids, especially respiratory depression. In

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addition, The Pharmacological Basis of Therapeutics (Goodman & Gilman, Tenth Edition) notes that for children under 6 months of age, especially those who are ill or premature, the pharmacokinetics and potency of opioids can be substantially altered and in some cases there is a significant risk of apnea. Thus, the petitioner would question the merits of exposing pediatric patients younger than 2 years of age to this serious adverse effect during the course of a clinical study. Further, Hydrocodone Bitartrate and Acetaminophen, in a dosage strength of 5 mg / 500 mg, is already available and this new dosage form is not expected to increase pediatric use.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR § 25.31.

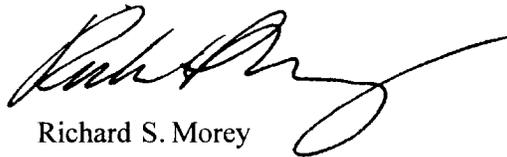
D. Economic Impact

The information will be provided upon request by the Agency.

E. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,



Richard S. Morey

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Attachments

1. Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).
Internet listing of Hydrocodone Bitrate / Acetaminophen
2. Professional Labeling for Vicodin® (Reference Listed Drug)
3. Proposed Labeling for Hydrocodone Bitartrate and Acetaminophen Orally
Disintegrating Tablets, 5 mg / 500 mg



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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Kleinfeld, Kaplan and Becker
Attention: Richard S. Morey
1140 Nineteenth St., N.W.
Washington, D.C. 20036-6606

Docket No. 02P-0233/CP1

Dear Mr. Morey:

This letter is in reference to your petition for Hydrocodone Bitartrate and Acetaminophen Orally Disintegrating Tablets, 5 mg/500 mg, approved on February 5, 2003. For your information, a waiver of the requirement for pediatric studies under PREA has been granted for this specific drug product. Therefore, the approval of your petition is re-instated.

On December 3, 2003, the "Pediatric Research Equity Act of 2003" (PREA) was signed into law. PREA requires that all applications for new active ingredients, new dosage forms, new indications, new routes of administration and new dosing regimens contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. PREA applies retroactively to applications submitted on or after April 1, 1999. Your petition is affected by this Act because it is an ANDA suitability petition that was approved for a change in dosage form and was submitted on or after April 1, 1999.

A copy of this letter will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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